Disclosures. **C. Sarrazin**, Abbott, AbbVie, BMS, Gilead, Janssen, Merck/MSD; Research Support: Abbott, Gilead, Janssen, Siemens: Board Member and Consultant, Consulting fee. Abbott, AbbVie, BMS, Gilead, Janssen, Merck/MSD, Roche, Siemens: Speaker's Bureau, Speaker honorarium. **T. Tran**, AbbVie, Bristol-Myers Squibb, Gilead, Janssen, Merck: Consultant, Grant Investigator and Research Contractor, Consulting fee, Research grant and Research support. **D. Dylla**, AbbVie, Inc.: Employee and Shareholder, Salary and Stock and/or options. **J. J. Feld**, AbbVie, Gilead, Janssen, Merck: Board Member, Consultant, Grant Investigator and Scientific Advisor, Consulting fee, Grant recipient and Research grant. **S. Arora**, Abbvie, Gilead: Grant Investigator and Research Contractor, Research grant and Research support. **D. Victor III**, AbbVie, Intercept: Investigator and Scientific Advisor, Consulting fee. **Y. B. Hu**, AbbVie Inc: Employee and Shareholder, Salary and Stock and/or options. **S. Wang**, AbbVie Inc.: Employee and Shareholder, Salary and Stock and/or options. **F. Mensa**, AbbVie Inc.: Employee and Shareholder, Salary and Stock and/or options. **D. L. Wyles**, AbbVie, Gilead, Merck, Tacere Therapeutics: Consultant, Grant Investigator, Research Contractor and Scientific Advisor, Consulting fee, Research grant and Research support.

1980. Efficacy of an Oral Vancomycin Loading Dose (LD) in the Treatment of Confirmed *Clostridium Difficile Infection* (CDI)

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Background. Over the past decade the incidence and severity of CDI has increased significantly. The 2018 IDSA Guidelines now recommends oral vancomycin 125 mg every 6 hours as the first-line therapy for initial occurrence of CDI. However, the optimal dosage of vancomycin is not well established. Pharmacokinetic data demonstrate that patients who receive 125 mg every 6 hours may have low fecal levels of vancomycin during the first 24 hours of therapy. Given that the fecal levels are relatively proportional to the dosage administered, a vancomycin LD may improve clinical outcomes. This study compared two vancomycin oral dosing regimens in patients with CDI.

Methods. A retrospective study evaluating pre and post-implementation of a 48-hour LD of vancomycin 500 mg every 6 hours was conducted. The control group included patients from January 2013 to January 2016. The intervention group included patients from February 2016 to December 2017, after the implementation of an LD as part of the order in the electronic medical record. Included subjects had confirmed CDI defined as diarrhea plus a positive *C. difficle* antigen and a positive rapid toxin by ELISA or positive cytotoxin. Subjects were exclude if they were <18 years of age, history of CDI in the past 90 days, received metronidazole within 24 hours of vancomycin initiation, or were treated for CDI in the past 28 days. The primary outcome was time to resolution of diarrhea defined as the interval, in days, from the start of treatment until the last unformed bowel movement. Secondary outcomes included clinical cure, defined as resolution of diarrhea and symptoms with no need for further treatment and recurrence of CDI.

Results. Three hundred ten patients were enrolled in the study with 155 patients in each arm. Time to resolution of symptoms was faster in the LD group compared with the control group (4 vs. 4.5 days; $P = 0.05$). There was no significant difference between the LD and control groups with respect to clinical cure (90% vs. 85%; $P = 0.17$); but patients <65 years had a higher clinical cure rate using the LD (95% vs. 84%; $P = 0.03$).

Conclusion. An oral vancomycin LD for CDI therapy was associated with a decrease in time to resolution of symptoms. Patients aged <65 years had improved clinical cure with the LD. Additional prospective studies are needed to clarify the optimal oral vancomycin dosing strategy.

Disclosures. **All authors:** No reported disclosures.

1981. Real-World Data on Safety and Effectiveness of Glecaprevir/Pibrentasvir for the Treatment of Patients With Chronic Hepatitis C Virus Infection on Opioid Substitution Therapy: Latest Results from the German Hepatitis C-Registry

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Background. The coformulated direct-acting antivirals glecaprevir/pibrentasvir (G/P) are approved to treat chronic hepatitis C virus (HCV) genotype 1–6 infection. In clinical trials, G/P demonstrated high efficacy, but real-world data in patients on opioid substitution therapy (OST), a population for which antiviral treatment is critical for HCV elimination, are limited. Here we report the first real-world data on the effectiveness and safety of G/P for OST patients within the German Hepatitis C-Registry (DHC-R).

Methods. The DHC-R is an ongoing, noninterventional, multicenter, prospective, monitored registry study. Data were collected between July 28, 2017 and February 9, 2018 from 104 sites in Germany. The analysis included adult HCV-infected patients who were treated with G/P according to the European Medicines Agency label. The primary endpoint was sustained virologic response at post-treatment week 12 (SVR12). Safety and tolerability were assessed in patients that completed treatment.

Results. As of February 9, 2018, 638 patients had initiated on-label treatment with G/P and are included in the baseline analysis. Patients on OST comprised 26% (168/638) of the baseline population, of which most patients were treatment-naive, without cirrhosis and had HCV genotype 1a or 3. Among patients with available SVR12 data, 96% (27/28) of OST patients and 97% (66/68) of non-OST patients achieved SVR12. There were no virologic failures: of three early discontinuations, one OST patient was lost to follow-up and two non-OST patients discontinued treatment due to adverse events (AE). In the modified intention-to-treat population which excluded non-virologic failures, SVR12 was 100% for both OST and non-OST patients. The safety population included 321 patients in total. Among OST patients, 2% (2/84) experienced serious AEs (SAE) without any treatment discontinuations due to AE/SAE.

Conclusion. In this real-world analysis, G/P treatment yielded favorable effectiveness and safety results in patients on OST. Updated data and SVR12 results will be presented.

Disclosures. **J. Reimer**, AbbVie, Bristol-Myers Squibb, Gilead, Janssen-Cilag, MSD: Board Member and Scientific Advisor, Educational grant and Speaker honorarium. **A. Stoehr**, AbbVie, Gilead, Janssen, MSD, ViiV: Consultant and Scientific Advisor, Consulting fee and Speaker honorarium. **U. Naumann**, AbbVie, Bristol-Myers Squibb, Gilead Sciences, Janssen, Mundipharma, MSD, Roche, ViiV: Board Member, Scientific Advisor and Speaker's Bureau, Consulting fee and Speaker honorarium. **G. Teuber**,: AbbVie, BMS, Janssen, Gilead, MSD: Consultant and Scientific Advisor, Consulting fee and Speaker honorarium. **C. Zamani**, AbbVie Inc.: Board Member and Scientific Advisor, Consulting fee. **S. Mauss**, AbbVie, Gilead, Falk, Janssen, MSD: Scientific Advisor and Speaker's Bureau, Consulting fee and Speaker honorarium. **N. Qurishi**, AbbVie, Gilead, Janssen, MSD, ViiV, Mundipharma, Hexal: Consultant and Scientific Advisor, Consulting fee and Speaker honorarium. **K. Lohmann**, AbbVie Inc.: Employee and Shareholder, Salary and Stock and/or options. **H. Kleine**, AbbVie Inc.: Employee and Shareholder, Salary and Stock and/or options. **A. Pangerl**, AbbVie Inc.: Employee and Shareholder, Salary and Stock and/or options. **S. Christensen**, AbbVie, Gilead, Indivior, Janssen-Cilag, MSD, ViiV: Consultant and Scientific Advisor, Consulting fee and Speaker honorarium.

1982. Multiplex PCR-Based Analysis of Enteric Pathogens in Faecal Samples from Patients with *Clostridium difficile* Infection in the Randomized, Controlled EXTEND Study Comparing the Efficacy of Extended-Pulsed Fidaxomicin With Vancomycin Therapy

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Background. Extended-pulsed fidaxomicin (EPFX) was equivalent to standard vancomycin (SV) for resolving *Clostridium difficile* infection (CDI) in the EXTEND study. Sustained clinical cure (SCC) at 30 days after end of treatment (EOT) was achieved in 124/177 (70%) patients receiving EPFX vs. 106/179 (59%) patients receiving SV (difference 11%; $P = 0.030$). The BioFire platform, a multiplex PCR-based method, was used to detect possible enteric co-pathogens in patients from EXTEND.

Methods. Patients aged ≥60 years with positive local test for CDI were randomized (1:1) to receive either EPFX (200 mg tablets, twice daily on Days 1–5 and once daily on alternate days on Days 7–25) or SV (125 mg capsules, four times daily on Days 1–10). Stool samples were collected from all patients at screening and analysed using the BioFire FilmArray Gastrointestinal (GI) panel (Biomérieux). The primary endpoint was the rate of SCC at 30 days after EOT, defined as clinical response (determined by the investigator) and no CDI recurrence. Patients were grouped according to BioFire results, and clinical outcomes were then compared using the chi-square test and logistic regression analyses.

Results. At screening, all patients tested positive for *C. difficile* toxin A/B by local laboratory test, and 286/332 patients tested positive for *C. difficile* by BioFire (Figure 1). SCC rates at 30 days after EOT, by baseline presence/absence of enteric